

Comments on EPA Proposed Rule Strengthening Transparency in Regulatory Science

Abigail Omojola, Breast Cancer Prevention Partners

My name is Abigail Omojola and I am here on behalf of Breast Cancer Prevention Partners to speak in strong opposition to the proposed rule and to urge the EPA to withdraw it immediately.

Breast Cancer Prevention Partners is a national organization committed to preventing breast cancer by eliminating exposures to chemicals and radiation that have been linked to an increased risk of the disease. We take great care and pride in ensuring that all of our public education, programs and policy advocacy are based on a strong foundation of peer-reviewed science.

Contrary to its stated intent, the proposed rule under consideration today would *not* serve to provide the public with greater “confidence in and understanding of” EPA’s regulatory decisions. Rather, it would deeply undermine the ability of the EPA to use all the best available science in its regulatory decisions, which, in turn, will negatively impact public health. In fact, it is hard *not* to come to the conclusion that the proposed rule is a strategy to disregard many studies that have shown negative impacts of chemical exposures on public health.

Breast cancer is a disease with complex causation and often a long latency period. Only about 10% of breast cancer diagnoses can be attributed solely to genetics. Breast cancer risk is a web of interactions between environmental exposures, genetics and lifestyle characteristics. Much of the data showing the connection between unsafe chemical exposures and breast cancer risk comes from laboratory studies. However, epidemiological studies, and in particular longitudinal studies, provide unique insights and important corroboration of these findings.

The proposed rule’s requirement that underlying data must be made public before the EPA can consider a study in agency decision-making will have the practical impact of eliminating many of these critical studies from the regulatory process. Epidemiological studies involve the collection of extensive and detailed individual health data and researchers have an ethical obligation to protect the confidentiality of that data. The elimination of these studies will result in less scientifically sound conclusions and, most importantly, the public health benefits they would provide.

An example of the kind of study this proposed rule could eliminate from the EPA’s regulatory process is the National Institute of Environmental Health Sciences’ Sister Study. From 2003 to 2009, the Sister Study enrolled 50,000 women whose sisters had breast cancer. Those women will be followed for a minimum of 10 years to study how genes and the environment interact to impact the risk of developing

breast cancer, leading to a greater understanding of ways to prevent both breast cancer and other diseases. It does not serve the public interest to hinder the EPA's ability to use this type of research in their regulatory decisions.

This proposed rule will not only undermine the use of previously conducted epidemiological studies; it will also damage the ability of researchers to conduct future studies. Recruitment of study participants will be severely undermined if people fear their personal information may be made publicly available. This is particularly true for vulnerable communities that are both disproportionately exposed to toxic chemicals and have historical reasons to distrust researchers. Yet, it is the exposures experienced by these communities, and the resulting health effects, that we most need to understand and address.

The integrity of scientific methodology is thoroughly reviewed at many points in the processes of designing, conducting and publishing scientific research. The competitive grant process; Institutional Review Board requirements; peer-review prior to publication; the expertise and judgment of career EPA scientists when considering the strength and relevance of studies included in EPA decisions; and finally review of those decisions and the underlying science by EPA's Science Advisory Board; all provide more than sufficient opportunities to assess the soundness of scientific studies. This proposed rule is not only damaging, it is unnecessary.

On behalf of the 1 in 8 women who will be diagnosed in their lifetime and the 40,000 lives that are lost each year in the U.S. to breast cancer, the EPA has an obligation to take action to *prevent* this devastating disease. This proposal takes a hard step away from that goal.

Thank you for the opportunity to provide this public comment urging the EPA to withdraw this misguided and damaging proposed rule.